K071237

510(k) Summary

Submitted by: Kensey Nash Corporation
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Jennifer J. Bosley, MBA, RAC
Regulatory Affairs Specialist
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JUN - 1 2007

Date Prepared: May 2, 2007

Device Trade Name: CopiOs™ Bone Void Filler
Common/Usual Name: Bone Void Filler
Proposed Classification: Resorbable Calcium Salt Bone Void Filler Device
21CFR § 888.3045
Class II, MQV—87Orthopedics

Device Description:
CopiOs™ Bone Void Fillers are resorbable rectangular sponges or powder discs manufactured from calcium phosphate and Type I bovine dermal collagen. CopiOs™ Paste, a compressed powder disc, forms a paste when mixed with autologous blood products using the supplied spatula. CopiOs™ devices are gamma-sterilized for single use and supplied in 1cc, 5cc and 10cc volumes.

Intended Use:
CopiOs™ Bone Void Filler, in combination with autologous blood products such as bone marrow, is intended for use only for filling bone voids or gaps of the skeletal system (i.e. extremities, pelvis, spine) that are not intrinsic to the stability of the bone structure. These voids may be a result of trauma or creation by surgeon. CopiOs Bone Void Filler is intended to be gently packed into the void or gap and will resorb during the course of the healing process.

Predicate Device:
K033679—CopiOs™ Bone Void Filler (Sponge), Kensey Nash Corp [Centerpulse Spine-Tech]

Substantial Equivalence:
CopiOs™ Paste is substantially equivalent to the legally marketed predicate device, CopiOs™ Sponge with regard to materials, processing, intended use and fundamental scientific technology.

Non-Clinical Testing:
CopiOs™ Paste has undergone non-clinical testing, including biocompatibility, migration resistance, pH, hydration and handling characteristics. Testing provides reasonable assurance of safety and effectiveness for its intended use and supports a determination of substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kensey Nash Corporation
% Ms. Jennifer J. Bosley, MBA, RAC
Regulatory Affairs Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

JUN - 1 2007

Re: K071237
Trade/Device Name: CopiOs™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: May 2, 2007
Received: May3, 2007

Dear Ms. Bosley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

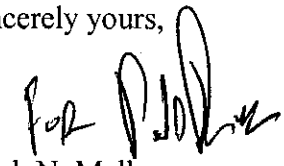
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K071237

Device Name: **CopiOs™ Bone Void Filler**

Indications For Use:

CopiOs™ Bone Void Filler, in combination with autologous blood products such as bone marrow, is intended for use only for filling bone voids or gaps of the skeletal system (i.e. extremities, pelvis, spine) that are not intrinsic to the stability of the bone structure. These voids may be a result of trauma or creation by surgeon. CopiOs Bone Void Filler is intended to be gently packed into the void or gap and will resorb during the course of the healing process.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071237